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NATIONAL CHILDHOOD VACCINE IMPROVEMENT ACT OF 1986

SEPTEMBER 24, 1986.—Ordered to be printed

Mr. HATCH, from the Committee on Labor and Human Resources, submitted the following

REPORT

[To accompany S. 827]

[Including cost estimate of the Congressional Budget Office]

The Committee on Labor and Human Resources, to which was referred the bill (S. 827) to amend the Public Health Service Act to provide for the compensation of children and others who have sustained vaccine-related injuries, and for other purposes, having considered the same, reports favorably thereon with an amendment in the nature of a substitute, and an amendment to the title, and recommends that the bill as amended do pass.

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I. SUMMARY OF BILL

The vaccine bill favorably reported by the Senate Labor and Human Resources Committee is based on Part C of S. 827, which is

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titled Assuring a Safer Childhood Vaccination Program in the United States. Its provisions include:

(1) The establishment of an Advisory Commission composed of parents, vaccine manufacturers and physicians that would supplement the existing federal commissions on vaccine to advise the Secretary on carrying out his mandate to develop safer childhood vaccines. The duties of this Advisory Commission include:

(a) studying and recommending ways to encourage availability of adequate supply of safe and effective childhood vaccines in the United States;

(b) a survey of the current programs and activities related to the gathering of information on adverse reactions associated with administration of childhood vaccines;

(c) recommending research priorities to the Secretary to enhance the safety and efficacy of childhood vaccines;

(d) a review of all medical and scientific information on the nature, circumstances and extent of the relationship, if any, between childhood vaccines and certain illnesses or injuries. If the childhood vaccine can be reasonably determined to cause or significantly contribute to the illness or conditions, the Commission shall specify the circumstances and time periods within which the first symptom or manifestation may occur after immunization;

(e) a study of risks to children associated with each childhood vaccine and recommendations regarding the circumstances under which any childhood vaccine should not be administered, the circumstances in which the immunization should be delayed, and the groups, categories, or characteristics of potential recipients who may be at a higher risk of adverse reactions than the general public.

(2) Mandatory recordkeeping by health providers of information regarding immunizations.

(3) Mandatory reporting of adverse reactions to the Secretary of HHS by health providers and vaccine manufacturers.

(4) A requirement that the Secretary of HHS review and update the contraindications noted for childhood vaccines.

(5) The development of parent information materials which explain the risks and benefits of immunization, the applicable laws governing immunization and a listing of possible reactions that the parents should monitor and report to their physicians.

(6) The authorization of $11 million in research for a safe pertussis vaccine.

(7) Authorization of $90 million for the nation's childhood immunization program.

(8) A requirement that the Centers for Diseases Control accumulate and maintain a 6 month stockpile of childhood vaccines.

(9) Authority for the Food and Drug Administration to recall lots of vaccines that are considered a threat to the public health.

II. Background and Need for Legislation

S. 827 is aimed at the improvement of vaccines and vaccine supplies. Vaccines induce immunity to specific diseases by administering or by inducing the body itself to produce antibodies and other

natural defense mechanisms. Those with vaccine induced immunity, when infected, develop no or only mild symptoms. As might be expected, vaccines potentially possess a high degree of effectiveness in preventing serious illness or death, coupled with a low incidence of serious side effects, and they have been instrumental in eradicating or controlling some of mankind's most devastating scourges.

Beginning with the first tentative steps to inoculate against smallpox in this country over two centuries ago, our physicians and, later, public health authorities, have continually sought to develop, improve, and expand the use of vaccines. Advances here and in other countries have brought spectacular results, particularly in the last few decades as additional vaccines have been developed. Beyond the worldwide eradication of smallpox, one of the signal achievements of modern medicine, we can be encouraged by the following accomplishments, largely the result of our childhood vaccination programs:

—Known Rubella cases in the United States fell from 57,868 cases with 29 deaths in 1969 to 2,325 cases with 4 fatalities in 1982.

—Reported U.S. measles cases dropped from 894,134 with more than 2,250 fatalities in 1941 to 1,497 cases and 2 deaths in 1983.

—Reported cases of mumps in this country decreased from 150,000 in 1968 to under 3,500 in 1983.

—The rate of diptheria cases, averaging more than 1,000 per year with an annual death rate of about 75 in the late 1950's, fell to 3 cases per year with either one or no deaths between 1980 and 1984.

—Tetanus cases in the U.S. decreased from 601 cases in 1948 to fewer than 95 cases in 1983.

—The incidence of paralytic poliomyelitis has practically ceased, falling from 57,000 cases in 1952 to fewer than 4 reported cases in 1984.

—Pertussis, or whooping cough, once a major childhood killer, has also been brought under control. From a peak of 265,269 cases with over 7,500 deaths in 1934, the incidence of pertussis decreased to fewer than 2,000 cases and only 4 deaths in 1982.

However, continuing vigilance is necessary if we are to maintain these gains. Public doubts about the advisability of pertussis vaccination, for example, have led to an increase in unvaccinated children in some areas and we are beginning to see a consequent rise in the pertussis rate.

The future holds great hope, particularly through the use of recombinant DNA technology, for the development of vaccines for diseases which are now treatable only through other methods. But we must not at the same time neglect the improvement of existing vaccines. While the incidence of adverse reactions to vaccines like that for pertussis is very small, reactions do exist, and occasionally still prove fatal. While the Committee does not question the necessity or benefit of public inoculation programs it has felt compelled to do all it can to further refine these vaccines to eliminate the risk of serious injury or death for those inoculated.

The Senate Labor and Human Resources Committee first considered the need for improvements in the nation's childhood vaccine

program on May 7, 1982 when the Subcommittee on Oversight and Investigations held a hearing on Immunization and Preventive Medicine. Testimony about the increasing price of childhood vaccines prompted an additional hearing on July 22, 1982 entitled Oversight on Immunization Costs.

The testimony at those hearings indicated that their were many unanswered questions regarding the safety of the pertussis vaccine. In an attempt to answer many of these questions, on September 23, 1982 Senator Hawkins introduced S. 2950, legislation calling for a study of the pertussis vaccine.

S. 2950 required the Secretary of Health and Human Services to review and report on the following areas: (1) Diagnosis, reporting and recordkeeping concerning the incidence and severity of pertussis and significant adverse reactions to pertussis vaccines; (2) Availability of techniques for the purification of, or extraction from, existing pertussis vaccine, in order to reduce the reactogenicity of such vaccines without rendering them unable to meet applicable potency standards; (3) Availability or development of procedures or techniques for identifying children who may be susceptible to significant adverse reactions to pertussis vaccines; (4) Current public and private efforts to develop and demonstrate clinically a pertussis vaccine which is safer than the pertussis vaccines currently used in the United States; (5) The association, if any, between pertussis vaccination and sudden infant death syndrome (SIDS) and the need for further study of such association; (6) The creation and operation of a Federal compensation program for individuals who are seriously injured as the result of adverse reactions to pertussis vaccine, including an evaluation of existing compensation programs in California and in foreign countries; and (7) Other administrative and legislative changes which may be necessary.

On December 21, 1982 Health and Human Services Secretary Schweiker wrote to Senator Hawkins agreeing to carry out the mandates of S. 2950 under his existing administrative authority. Thus on February 21, 1983 the National Institutes of Allergy and Infectious Disease released a request for proposal for development of an acellular pertussis vaccine. On April 26, 1983 the Department of Health and Human Services held a public meeting on the pertussis vaccine to take comments from the public.

The Interagency Group to Monitor Vaccine Production, Development and Usage presented its report and recommendations to the full Senate Labor and Human Resources Committee on July 23, 1983. A follow-up report detailing progress on implementing the Group's reforms and recommendations was sent to the Senate Labor and Human Resources Committee on November 15, 1983.

The introduction of S. 2950 and the subsequent report and recommendations of the Pertussis Task Force did prompt significant administrative improvements and additional resources allocated to pertussis and pertussis vaccine. But the report also confirmed the need for safer vaccines and acknowledged that further work and research were needed to identify high risk children, improve reporting of adverse reactions, communicate information about risks and benefits of immunization to parents and encourage more research into the pertussis vaccine. The deficiencies in the current system that were highlighted in the Pertussis Task Force Report,

especially the lack of consensus on the the issue of liability and compensation for adverse reactions to childhood vaccines, prompted Senator Hawkins to introduce the S. 2117, the National Childhood Vaccine Injury Compensation Act, on November 17, 1983. Full Committee hearings on the National Childhood Vaccine Injury Compensation Act, were held on May 3, 1984 by the Senate Labor and Human Resources Committee.

As predicted by witnesses at that hearing, it was not long before the availability of key vaccines was jeopardized. On June 13, 1984 Wyeth Laboratories, one of three pharmaceutical manufacturers of the Diptheria-Tetanus-Pertussis vaccine (DPT) announced that it was ceasing distribution of the DPT vaccine. During the summer of 1984, another of the pharmaceutical manufacturers of the DPT vaccine, Connaught Laboratories, was unable to negotiate satisfactory insurance coverage for its vaccines, and limited its distribution to large contracts with public health departments and hospitals.

On July 6, 1984 the third pharmaceutical manufacturer of DPT vaccine, Lederle Laboratories, announced that it would increase its production capacity to insure adequate supplies of vaccines, but it also announced that it was raising the cost of its DPT vaccine to $2.80 a dose or $42.00 for a vial of 15 doses.

Nevertheless, the production increase took some time and on December 13, 1984 the Centers for Disease Control issued a report announcing a shortage of the DPT vaccine and asked doctors to delay DPT booster shots for older children to ensure that there would be enough vaccine to immunize infants. This crisis lasted for approximately six months.

In the 98th Congress, a revised version of the National Childhood Vaccine Injury Compensation Act was introduced by Senator Hawkins on April 2, 1984. This bill addressed victim's compensation and tort reform issues and became the basis for further hearings and discussions. Committee members active on this issue have consistently attempted to negotiate a version of the legislation which provides expedited, simplified recovery procedures for victims of adverse vaccine reactions while at the same time rendering damages predictable and reasonable so that manufacturers would again be able to obtain insurance, and the price and availability of vaccines could be maintained at acceptable levels.

However, these issues have proved difficult to resolve. Thus, to make sure that the Senate would have the opportunity to consider constructive steps which could command consensus, Senator Hawkins proposed a substitute amendment to S. 827 during the Committee's July 30, 1986 executive session. This substitute, which has broad bipartisan support, leaves for resolution in the 100th Congress the still pressing issues of victim's compensation and tort reform. It focuses on a number of worthwhile additions to current law, which will help safeguard the vaccine supply, improve our knowledge about adverse reactions and assist in the development of safer vaccines.

While S. 827 as amended does not address the weightier liability issues, the Committee feels there is no reason to postpone enactment of the S. 827 substitute's positive provisions until those issues are resolved sometime in the future. We need a larger stockpile of vaccines; we need more information on adverse reactions; we need

to accelerate our quest for safer vaccines. S. 827, as reported from Committee, will accomplish these urgent public health purposes.

The Committee wishes to acknowledge the continuing efforts of the Department of Health and Human Services to find better approaches to the vaccine challenge. In December of 1985, the PHS Interagency Vaccine Group made a two week visit to Japan to review Japanese data on the use of acellular pertussis vaccines. While the Japanese experience is encouraging, the Group found the Japanese data lacking in information on safety and efficacy of the acellular products when used in infants. This is because the Japanese begin immunization for pertussis at 2 years of age, while U.S. pediatricians begin immunization of children at 2 months of age.

Further, the National Institutes of Health have research programs focused on pertussis and pertussis vaccine. Efforts through the NIAID Accelerated Development of New Vaccines program have lead to field trials in Sweden of two acellular pertussis vaccines, that are similar to those widely used in Japan for the past 4 years. The trials are proceeding with 3,700 children between the ages of 6 and 8 months already having been vaccinated. In addition, an American manufacturer has combined bulk accellular pertussis component from a Japanese manufacturer with its diphtheria and tetanus toxoids, and a clinical trial with this DTP vaccine was completed at the NIAID vaccine evaluation units. The initial results were promising, indicating that the study vaccine appeared less reactogenic while maintaining immunogenicity when given as a booster immunization. Further research is underway, and should be materially assisted by the passage of S. 827.

III. Text of Bill as Reported

Strike out all after the enacting clause and insert in lieu thereof the following:

A BILL To amend the Public Health Service Act to provide for the compensation of children and others who have sustained vaccine-related injuries, and for other purposes

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled, That this Act may be cited as the "National Childhood Vaccine Improvement Act of 1986".

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"TITLE XXI--ASSURING A SAFER CHILDHOOD VACCINATION PROGRAM IN THE UNITED STATES

"Sec. 2101. Advisory Commission on Childhood Vaccines.
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FINDINGS AND PURPOSE

Sec. 2. (a) The Congress finds that:

(1) There has been a long-standing effort by the Federal Government to promote childhood vaccinations against communicable diseases and to encourge States to adopt and enforce mandatory preschool vaccination laws. As a result, all fifty States and the District of Columbia require, with limited exceptions, that children receive certain childhood vaccines as a condition of entry into school.

(2) While the childhood vaccination programs implemented as a result of these efforts have prevented death and reduced suffering from once common communicable diseases such as polio, these same programs have, in an unknown number of cases, caused or significantly contributed to the injury, illness, disability, or even death of some inoculated children and others.

(3) Because communicable diseases are a national problem, because the primary thrust for childhood vaccination programs has come from the Federal Government, and because childhood vaccine-related injuries which may tend to undermine the public's confidence in these vaccination programs are a national concern, there is a national need for, and responsibility to establish a system to encourage the production of the safest possible childhood vaccines.

(b) The purposes of this title are—

(1) to establish mechanisms and create incentives to reduce the risks associated with presently available childhood vaccines; and

(2) to promote development and dissemination to parents in understandable terms of increased and improved information on the risks and benefits of available childhood vaccines and other relevant information.

CHILDHOOD VACCINE IMPROVEMENT

SEC. 3. The Public Health Service Act is amended—

(1) by redesignating sections 2101 through 2103 as sections 3 through 5, respectively;

(2) by redesignating sections 2106 through 2115 as sections 6 through 15, respectively;

(3) by amending the heading for title I to read as follows:

"TITLE I—GENERAL PROVISIONS";

(4) by striking out the heading for title XXI; and

(5) by inserting after title XX the following new title:

"TITLE XXI—ASSURING A SAFER CHILDHOOD VACCINATION PROGRAM IN THE UNITED STATES

"ADVISORY COMMISSION ON CHILDHOOD VACCINES

"SEC. 2101. (a) There is established the Advisory Commission on Childhood Vaccines. The members of the Commission shall be appointed by the Secretary, in consultation with the National Academy of Sciences. At least one member of the Commission shall be an individual who is engaged in vaccine research or in the manufacture of vaccines or who is a physician. At least one member of the Commission shall be an individual who is a member of an organization of parents concerned with vaccine immunizations. At least one member of the Commission shall be an individual who is a representative of State or local health agencies or public health organizations.

"(b) The members of the Commission shall select a chairman from among the members. The Commission shall first meet within 30 days after all members of the Commission are appointed, and thereafter shall meet at the call of the chairman, but not less often than three times per year.

"(c) Members of the Commission who are officers or employees of the Federal Government shall serve as members of the Commission without compensation in addition to that received in their regular public employment. Members of the Commission who are not officers or employees of the Federal Government shall each receive the daily equivalent of the rate in effect for grade GS-18 of the General Schedule for each day (including traveltime) they are engaged in the performance of their duties as members of the Commission. All members, while so serving away from their homes or regular places of business, may be allowed travel expenses, including per diem in lieu of subsistence, in the same manner as such expenses are authorized by section 5703, title 5, United States Code, for employees serving intermittently.

"(d) The Secretary shall—

"(1) designate a senior member of the Secretary's staff to act as Executive Director of the Commission, and

"(2) provide the Commission with such full-time professional and clerical staff, such information, and the services of such consultants as may be necessary to assist the Commission in carrying out effectively its functions under this section.

"(e) The Commission shall—

"(1) study and recommend ways to encourage the availability of an adequate supply of safe and effective childhood vaccination products in the United States, with special emphasis on assisting the Secretary in implementing the Secretary's responsibilities under section 2105, regarding the need for childhood vaccination products that result in fewer or no significant adverse reactions;

"(2) survey and analyze Federal, State, and local programs and activities relating to the gathering of information on injuries associated with the administration of childhood vaccines, including the adverse reaction reporting requirements of section 2102, and advise the Secretary on means to obtain, compile, publish, and use credible data related to the frequency and severity of adverse reactions associated with childhood vaccines;

"(3) recommend research priorities and other measures the Secretary should take to enhance the safety and efficacy of childhood vaccines and to carry out this title; and

"(4) carry out subsections (f) and (g).

"(f)(1) Not later than 3 years after the date of enactment of this title, the Commission shall complete a review of all relevant medical and scientific information on—

"(A) the nature, circumstances, and extent of the relationship, if any, between vaccines containing pertussis (including whole cell, extracts, and specific antigens) and hemolytic anemia, hypsarrhythmia, infantile spasms, Reye's syndrome, peripheral mononeuropathy, death classified as sudden infant death syndrome, aseptic meninigitis, juvenile diabetes, autism, learning disabilities, hyperactivity, and such other illnesses and conditions as the Commission may choose to review; and

"(B) the potential relationship between radiculoneuritis and MMR and other vaccines containing rebella.

"(2) The review under paragraph (1) shall include notice and opportunity for a public hearing and consideration of written information submitted by the public.

"(3) Not later than 3 years after the date of enactment of this title, the Commission shall make and publish the following specific findings or determinations:

"(A) Whether each of the illnesses or conditions listed in subparagraph (A) or (B) of paragraph (1), as the case may be, can reasonably be determined in some circumstances to be caused or significantly contributed to by the vaccines specified in such subparagraph.

"(B) For each illness or condition for which a finding of causation or contribution is made under subparagraph (A), the circumstances under which such causation or contribution can reasonably be determined to occur.

"(C) For each illiness or condition for which a finding of causation or contribution is made under subparagraph (A), the time periods within which the first symptom or manifestation of onset of each such illness or condition can reasonably be determined to occur after pertussis vaccination.

"(g) As soon as practicable, but not later than 1 year after the date of enactment of this title, the Commission shall—

"(1) conduct and support a broad study of the risks to children associated with each childhood vaccine; and

"(2) make recommendations to the Secretary concerning—

"(A) the circumstances under which any childhood vaccine should not be administered;

"(B) the circumstances under which administration of any childhood vaccine should be delayed beyond its usual time of administration; and

"(C) the groups, categories, or characteristics of potential recipients of any childhood vaccine who may be at significantly higher risk of major adverse reaction to such childhood vaccine than the general population of potential recipients.

"(h) For the activities of the Commission under this title, there are authorized to be appropriated such sums as may be necessary for each of the fiscal years 1987, 1988, 1989, 1990, and 1991.

"RECORDING AND REPORTING OF INFORMATION

"SEC. 2102. (a) Each health care provider who administers a childhood vaccine to any individual shall record, or insure that there is recorded, in such individual's permanent medical record (or in a permanent office log or file to which the individual, parent, or legal guardian shall have access upon request) with respect to each such childhood vaccine—

"(1) the date of administration of the childhood vaccine;

"(2) the manufacturer and lot number of the childhood vaccine;

"(3) the name of the health care provider administering the childhood vaccine; and

"(4) any other identifying information on the childhood vaccine required pursuant to regulations promulgated by the Secretary.

"(b)(1) Any health care provider who, after the date of enactment of this title, administers a childhood vaccine and who is notified or otherwise becomes aware that the recipient of the childhood vaccine has suffered a complication of immunization shall comply with the reporting requirements of paragraph (2).

"(2) Any health care provider to whom this subsection applies shall, as expeditiously as practicable, report to the Centers for Disease Control the occurrence of a complication of immunization and all other information relevant to such complication, including—

"(A) a specification of the type of childhood vaccine administered;

"(B) the time period after administration of the childhood vaccine within which such complication occurred;

"(C) the manufacturer and lot number of the childhood vaccine; and

"(D) the information described in paragraphs (3) and (4) of subsection (a).

"(3) If—

"(A) the recipient of a childhood vaccine suffers a complication of immunization;

"(B) such complication occurs within 30 days after the administration of the childhood vaccine; and

"(C) the health care provider receives oral or written notification or otherwise becomes aware of the occurrence of such complication,

the health care provider shall record, or insure the recording of, the symptom or manifestation of the complication and all other relevant information in the childhood vaccine recipient's permanent medical record.

"(4) Each health care provider and vaccine manufacturer shall report to the Secretary such information as may be required, by regulation promulgated by the Secretary, to be reported, respecting—

"(A) possible occurrences, with respect to any childhood vaccine, of—

"(i) illnesses, disabilities, injuries, or conditions relating to the administration of such childhood vaccine; and

"(ii) symptoms and manifestations of such illnesses, disabilities, injuries, or conditions; and

"(B) the time periods after the inoculation of such childhood vaccines within which such possible occurrences of illnesses, disabilities, injuries, symptoms, and manifestations may occur.

"(c)(1) Information which is in the possession of the Federal Government and State and local governments under this section and which may identify an individual shall not be made available under section 552 of title 5, United States Code, or otherwise, to any person except—

"(A) the individual who received the childhood vaccine; or

"(B) the parent, legal guardian, or authorized legal representative of such individual.

"(2) For purposes of this section, the term 'information which may identify an individual' shall be limited to the name, street address, telephone number, and actual medical records of the individual who received a childhood vaccine, and of that individual's parent or legal guardian, and shall not include the locality and State of inoculation, the name of the health care provider who administered the childhood vaccine, the date of the vaccination, or information concerning any reported symptom, manifestation, illness, disability, injury, or condition.

"(3) Except as provided in paragraph (1), all information reported under this section shall be available to the public.

"(d) Compliance by a physician or other health care provider with requirements of this section shall not be construed as an admission of liability by such physician or other health care provider and the fact of such compliance shall not be admitted in evidence for the purpose of establishing culpability of any such physician or health

care provider in any civil action in tort brought against such physician or other health care provider. The preceding sentence does not preclude the admission into evidence in any civil action in tort of the content of such recorded or reported information if the individual with respect to whom the record or report was made consents to such admission.

"RULES WITH RESPECT TO CHILDHOOD VACCINE ADMINISTRATION

"SEC. 2103. (a)(1) After receiving and considering the recommendations of the Commission under section 2101(q), the Secretary shall by rule, after notice and opportunity for public hearing and consideration of all relevant medical and scientific information, specify—

"(A) the circumstances under which any childhood vaccine should not be administered;

"(B) the circumstances under which administration of any childhood vaccine should be delayed beyond its usual time of administration; and

"(C) the groups, categories, or characteristics of potential recipients of any childhood vaccine who may be at significantly higher risk of major adverse reaction to such childhood vaccine than the general population of potential recipients.

"(2) The Secretary shall periodically, but at least every 3 years after promulgating the rule required under paragraph (1), review and revise such rule in accordance with the procedures set forth in such paragraph, unless the Secretary finds that on the basis of all relevant information no revision of such rule is warranted and publishes such finding in the Federal Register.

"(b) The Secretary shall widely disseminate the information contained or referenced in the rule required under subsection (a), to—

"(1) physicians and other health care providers;

"(2) professional health associations;

"(3) State and local governments and agencies; and

"(4) other relevant entities.

"PARENT INFORMATION

"SEC. 2104. (a) Not later than 1 year after the date of enactment of this title, the Secretary shall develop parent information materials for distribution by health care providers to the parents or legal guardians of any child receiving a childhood vaccine.

"(b) Such materials shall be developed—

"(1) after notice to the public and an opportunity for a public hearing; and

"(2) in consultation with the Commission, appropriate health care providers and parent organizations, the Food and Drug Administration, and the Centers for Disease Control.

"(c) The information in such materials shall be presented in understandable terms and shall include—

"(1) the frequency, severity, and potential longterm effects of the disease to be prevented by the childhood vaccine;

"(2) the symptoms or reactions to the childhood vaccine which, if they occur, should be brought to the immediate attention of the health care provider;

"(3) precautionary measures parents should take to reduce the risk of any major adverse reactions to the childhood vaccine that may occur;

"(4) early warning signs or symptoms to which parents should be alert as possible precursors to such major adverse reactions;

"(5) a description of the manner in which parents should monitor such major adverse reactions, including a form on which reactions can be recorded to assist parents in reporting information to appropriate authorities;

"(6) a specification of when, how, and to whom parents may report any major adverse reaction;

"(7) the contraindications to (and bases for delay of) the administration of the childhood vaccine;

"(8) an identification of the groups, categories, or characteristics of potential recipients of the childhood vaccine who may be at significantly higher risk of major adverse reaction to the childhood vaccine than the general population;

"(9) a summary of any relevant State and Federal laws concerning the childhood vaccine, including information on the number of vaccinations required for school attendance and the schedule recommended for such vaccinations; and

"(10) such other relevant information as may be determined by the Secretary.

"MANDATE FOR SAFER CHILDHOOD VACCINES

"SEC. 2105. (a) The Secretary shall—

"(1) promote the development or refinement of childhood vaccines that result in fewer and less serious adverse reactions; and

"(2) make or assure improvements in, and otherwise to use the authorities of the Secretary with respect to, the licensing, manufacturing, processing, testing, labeling, warning, use instructions, distribution, storage, administration, field surveillance, adverse reaction reporting, and recall of reactogenic lots or batches, of childhood vaccines, and research on childhood vaccines, in order to reduce the risks of adverse reactions to childhood vaccines.

"(b) Within 2 years after the date of enactment of this Act, and every 2 years thereafter, the Secretary shall prepare and transmit to the Committee on Labor and Human Resources of the Senate and the Committee on Energy and Commerce of the House of Representatives a report describing the actions taken pursuant to subsection (a) during the preceding 2-year period.

"(c) Not later than 1 year after the date of enactment of this title and after consultation with the Commission and with other appropriate entities, the Secretary shall review the warnings, use instructions, and precautionary information presently issued by manufactuers of diphtheria, pertussis, tetanus, measles, mumps, rubella, and polio vaccines and shall determine whether such warnings, instructions, and information adequately warn health care providers of the nature and extent of dangers by such vaccines. If the Secretary determines such warnings, instructions, and information are inadequate for this purpose in any respect, the Secretary shall at the same time require the manufacturers to revise and reissue such warnings, use instructions, and precautions as expeditiously as practical, but not later than 18 months after the date of enactment of this title. In conducting the review by this subsection, the Secretary shall request comments from the public.

"RESEARCH FOR A SAFE PERTUSSIS VACCINE

"SEC. 2106. (a) The Secretary shall conduct studies to identify and develop new, safe, and effective pertussis vaccines, including—

"(1) laboratory studies of the immune response to, and diagnosis of, pertussis;

"(2) phase I safety and immunogenicity studies;

"(3) field trials of the safety and efficacy of new pertussis vaccines; and

"(4) epidemiologic studies of the incidence of serious reactions following immunization with new pertussis vaccines.

"(b) To carry out this section, there are authorized to be appropriated $1,000,000 for fiscal year 1987 and $1,000,000 for fiscal year 1988.

"REPORTS RELATING TO CHILDHOOD VACCINES

"SEC. 2107. (a) The provisions of section 505(k) of the Federal Food, Drug, and Cosmetic Act with respect to records required to be maintained and reports required to be made by applicants, and the requirements imposed by regulations issued under that section, shall apply to persons holding licenses under section 351 of the Public Health Service Act for childhood vaccines.

"(b) The Secretary shall take appropriate actions to coordinate the receipt, collection, and evaluation of reports submitted to the Centers for Disease Control under section 2102 and reports submitted to the Food and Drug Administration under this section in order to avoid, insofar as practicable, duplicate reporting of the same events resulting from the administration of vaccines and in order to ensure that all such reports are available for evaluation by the Centers for Disease Control.

"DEFINITIONS

"SEC. 2108. For purposes of this title:

"(1) The term 'Commission' means the Advisory Commission on Childhood Vaccines established under section 2101.

"(2) The term 'childhood vaccine' means a vaccine against measles, mumps, rubella, diphtheria, pertussis, tetanus, or polio.

"(3) The term 'health care provider' means any licensed health care professional, organization, or institution, whether public or private (including Federal, State, and local departments, agencies, and instrumentalities) under whose authority a childhood vaccine if administered.

"(4) The term 'medical and scientific information' includes epidemiologic, clinical, biostatistical, pathological, toxicologic, and other laboratory data and case study information, observations, studies, and reports in peer-reviewed literature

or official government publications, as well as relevant unpublished information, data, studies, and observations.

"(5) The term 'MMR' means a vaccine containing material intended to prevent or confer immunity against measles, mumps, and rubella.

"(6) The term 'vaccine manufacturer' means any corporation, organization, or institution, whether public or private (including Federal, State, and local departments, agencies, and instrumentalities), which manufactures, processes, or distributes under its label any childhood vaccine, except that for purposes of section 351, such term shall include the manufacturer's sales or distribution subsidiary or representatives.

"SEVERABILITY

"SEC. 2109. In the event any portion of this title is declared or held unconstitutional or invalid, all remaining portions of this title shall remain unaffected, and in force and effect.".

TECHNICAL AMENDMENTS

SEC. 4. Sections 217(b), 217(c), and 465(f) of the Public Health Service Act are each amended by striking out "2101" and inserting in lieu thereof "3".

RECALL AUTHORITY

SEC. 5. Subsection (d) of 351 of the Public Health Service Act is amended—

(1) by inserting "(1)" after "(d)"; and

(2) by adding at the end thereof the following new paragraph:

"(2)(A) Upon a determination that a batch, lot, or other portion of a product licensed under this section presents an imminent hazard to the public health, the Secretary shall, after opportunity for an expedited hearing, issue, in any case necessary to protect the public health, an order requiring the immediate recall of such batch, lot, or other portion of such product.

"(B) Any violation of a recall order issued pursuant to subparagraph (A) shall subject the violator to a civil penalty of up to $100,000 per day of violation.".

AUTHORIZATION FOR IMMUNIZATION PROGRAM

SEC. 6. Section 317(j)(1) of the Public Health Service Act is amended by striking out "$65,000,000" and inserting in lieu thereof "$90,000,000".

VACCINE STOCKPILE

SEC. 7. The Secretary of Health and Human Services, through the Centers for Disease Control, shall acquire and maintain an amount of vaccines sufficient to provide vaccinations over a 6-month period.

Amend the title so as to read:

A bill to amend the Public Health Service Act to provide for the improvement of childhood vaccines.

IV. COMMITTEE HEARINGS

The Subcommittee on Investigations and General Oversight conducted a hearing on May 7, 1982 on Immunization and Preventive Medicine. The witnesses at this hearing included Dr. William H. Foege, Director, Centers for Disease Control, accompanied by Dr. David Fraser, the Assistant Director for Medical Science, Center for Infectious Diseases, Centers for Disease Control; Dr. Alan Hinman, Director, Immunization Division, Centers for Disease Control, Atlanta, GA; and Dr. Harry Meyer, Director, Bureau of Biologics, and Director-Designate, Bureau of Drugs, Food and Drug Administration, Bethesda, MD. Also, Mrs. Marge Grant and Mrs. Kathi Williams, on behalf of Dissatisfied Parents Together, and Monty Preiser, Esq., Presier and Wilson; Robert H. Parrott, M.D., director, Children's Hospital, Washington, D.C.; Dr. Vincent A.

Gulginiti, chairman, Committee on Infectious Diseases, American Academy of Pediatrics; Dr. Shirley Fannin, Chief, Acute Communicable Disease Control, County of Los Angeles, Department of Health and Human Services; and Dr. Alfred Munzer, American Lung Association, Washington Adventist Hospital.

The Subcommittee on Investigations and General Oversight conducted a hearing on July 22, 1982 on the oversight of immunization costs. Witnesses at this hearing included: Dr. Henry F. Cooney, Special Assistant to the Chief of Administration, Pan American Health Organization, accompanied by Dr. Jorge Litvak, Chief, Division of Disease Prevention and Control, Pan American Health Organization; Walter Umstead, Chief of Procurement, Pan American Health Organization; and Dr. Gaston Tawil, Regional Adviser, Biologics, Pan American Health Organization. Also, Lewis H. Sarett, Senior Vice President, Science and Technology, Merck & Co., accompanied by Richard D. Morr, Director of Marketing and Planning for Vaccines, Merck & Co.; and Jack Bowman, President, and Francis R. Cano, Lederle Laboratories, American Cyanimid. Also, Stephen King, Department of Health and Rehabilitative Services; Dale Morris, New York State Department of Health; and Donald Biemiller, Program Coordinator, Richmond, VA, accompanied by Leonard Lao, Procurement Officer, Division of Purchasing, Richmond, VA. Also, Alan R. Hinman, Director, Immunization Division, Center for Prevention Services, Centers for Disease Control, accompanied by David Rowe, Director, Procurement and Grants Office, Center for Disease Control; Dennis Styrsky, Chief, Marketing Division for Pharmaceutical Products, Veterans' Administration; and Donald Stenhouse, Acting Chief, Program Operation Section, Immunization Division, Centers for Disease Control.

The full Labor and Human Resources Committee conducted hearings on July 22, 1983 on the Task Force Report on Pertussis; May 3, 1984 on the National Childhood Vaccine-Injury Compensation Act; and on the National Childhood Vaccine-Injury Compensation Act of 1985 on July 18, 1985 and December 19, 1985.

Witnesses at the July 22, 1983 hearing on the Task Force Report on Pertussis included: Dr. Walter R. Dowdle, Director, Center for Infectious Diseases, Centers for Disease Control, accompanied by Dr. William S. Jordan, Microbiology and Infectious Disease Program, National Institute of Allergy and Infectious Diseases, National Institutes of Health; Dr. John C. Petricciani, Director, Office of Biologics, FDA; and Dr. Kenneth J. Bart, Chief, Surveillance, Investigations, and Research Branch, Division of Immunization, Center for Prevention Services, Centers for Disease Control. Also testifying were Mrs. Marge Grant, Chairman, Research Committee of Citizens for Free Choice in Immunizations, State of Wisconsin; Wendy Scholl, Palm Harbor, FL; Jeffrey H. Schwart, President, Dissatisfied Parents Together; Dr. Martin H. Smith, representing the American Academy of Pediatrics; Robert Kaufman, trial attorney, Gaylord, MI.

Witnesses at the May 3, 1984 hearing on the National Childhood Vaccine-Injury Compensation Act included: Dr. Edward M. Brandt, Jr., Assistant Secretary of Health, Department of HHS, accompanied by Dr. James O. Mason, Director, Center for Disease Control; and Dr. Alan Hinman, Immunization Division, Centers for Disease

Control; Andrew Dodd, attorney; Kenneth L. Eaton, Michigan Department of Public Health, accompanied by Vincent J. Leone, Assistant Attorney General, State of Michigan; Marge Grant, Chairman, Research Committee for Free Choice in Immunizations, State of Wisconsin; Dr. Stephen H. King, Florida Department of Health and Rehabilitative Services; John E. Lyons, President, Merck Sharp & Dohme, accompanied by William B. Freilich, Counsel. Robert A. McConnell, Assistant Attorney General, U.S. Department of Justice; Dr. Alan R. Nelson, American Medical Association; Dr. Jonas Salk, the Salk Institute for Biological Studies; Jeffrey H. Schwartz, Dissatisfied Parents Together; Dr. Martin H. Smith, President-Elect, American Academy of Pediatrics; Dr. Hadley Wilson, Department of Medicine, Vanderbilt University.

Witnesses at the July 18, 1985 hearing on the National Childhood Vaccine-Injury Compensation Act of 1985 included: Barbara Loe Fisher, Vice President, Dissatisfied Parents Together; Marge Grant, President, Determined Parents to Stop Hurting Our Tots; Robert Johnson, President, Lederle Laboratories, accompanied by Ronald Cracas, Legal Counsel, American Cyanimid Co.; David J. Williams, Vice President, Connaught Laboratories, Inc., accompanied by Carl Greco, General Counsel, and Stephen White; Charles F. Hagan, Vice President and General Counsel, American Home Products Corp., accompanied by Daniel Shaw, Vice President for Medical Affairs, Wyeth Laboratories. Also, Jeffrey H. Schwartz, President, Dissatisfied Parents Together; Dr. James O. Mason, Acting Assistant Secretary for Health and Director, Centers for Disease Control, Department of HHS, accompanied by Dr. Alan Hinman, Centers for Disease Control; Robert Willmore, Deputy Assistant Attorney General, Department of Justice; Dr. Alan R. Neslon, Vice Chairman, Board of Trustees, American Medical Association; Anthony M. Colantoni, attorney; Dr. Martin H. Smith, President, American Academy of Pediatrics; Dr. Bailus Walker, Massachusetts Commissioner of Public Health.

Witnesses at the December 19, 1985 hearing on part two of the Vaccine-Injury Compensation Act of 1985 included: Dwight A. Corrin, Esq.; Dr. Marshall S. Shapo, professor, Northwestern University School of Law; Anthony Colantoni, Esq.; Dr. Martin Smith, President, American Academy of Pediatrics; and Dr. Richard M. Narkewicz, pediatrician and member, American Academy of Pediatrics.

V. Committee Views

ADVISORY COMMISSION

In order to give a higher priority to the development of knowledge and policy concerning childhold vaccines and in particular the development of safer vaccines, S. 827, as reported, establishes an Advisory Commission within the Department of Health and Human Resources. The Committee intends that the membership of the Advisory Commission on Childhood Vaccines be equitably selected from among individuals who are engaged in vaccines research or the manufacture or administration of vaccines; members of organizations of parents concerned with vaccine immunization

and representatives of State and local health agencies or public health organizations.

The Committee is aware of the work of the Interagency Task Force on Vaccine, Development, Production and Usage and the Advisory Committee on Immunization Practices in coordinating the traditional roles of the National Institute of Allergy and Infectious Disease (NIAID), the Food and Drug Administration (FDA) and the Centers for Disease Control (CDC). The Committee's primary goal in authorizing this Advisory Commission is to provide the Secretary with a perspective that is not available through his Interagency Task Force on Vaccine Production Development and Usage. The need for such an Advisory Commission was noted in a recent report by the Institute of Medicine entitled "Vaccine Supply and Innovation".

The Report noted:

> The lack of a formal mechanism to promote cooperation in the innovation, production, and use of vaccines limits the benefits obtainable from existing immunization programs and hampers the development of new programs. The problems associated with the absence of such a mechanism are primarily those of omission rather than commission: They include delay or inefficiency in achieving desired outcomes and failure to tackle problems for which no existing group has direct responsibility.
>
> The history of earlier ad hoc groups convened to address problems related to vaccine availability and use has been discouraging. Specific actions envisaged by such groups have not been implemented for reasons unrelated to their potential utility. When these groups disbanded, attention focused on their activities waned.
>
> To overcome these difficulties, the committee recommends the establishment of a national vaccine commission. This commission would monitor all aspects of immunization efforts in the United States. One of its prmary responsibilities would be early identification of potential problems affecting vaccine supply. It also would help to educate and inform the public, physicians, and government decision makers about the effects of various immunization actions and policies. When necessary, the commission would become an impartial broker to promote the availability of needed vaccines and to coordinate collaborative activities for which no suitable mechanism exists.

The main duties of the Advisory Commission are to study and recommend ways to encourage the availability of an adequate supply of safe and effective childhood vaccination products in the U.S. with special emphasis on assisting the Secretary in developing and encouraging childhood vaccine products that result in fewer or no significant adverse reactions. The Commission is to survey and analyze the current methods related to the gathering of information on adverse reactions to childhood vaccines and advise the Secretary on methods to improve the collection of accurate data.

The Commission is also charged with advising the Secretary on research priorities and measures that will enhance the safety and

efficacy of childhood vaccines. No later than one year after the enactment of the bill the Commission is directed to conduct and support a broad study of the risks to children associated with each childhood vaccine and make recommendations regarding the circumstances in which any childhood vaccine should not be administered, the circumstances under which any vaccine should be delayed beyond the time of its otherwise recommended date of administration, and the groups, categories or characteristics of potential recipients of any childhood vaccines who may be at a higher risk of significant adverse reaction than the general population.

Another duty of the Advisory Commission is to complete a review of all relevant medical and scientific information on a variety of medical conditions and illnesses to determine the relationship, if any, of childhood vaccines and these illnesses and conditions. After this review is complete, the Advisory Commission shall publish its findings on whether each of the illnesses or conditions can reasonably be determined to be caused or significantly contributed to by the childhood vaccines. If a finding of causation or contribution is made on an illness or condition, then the Advisory Commission shall publish the circumstances under which the causation or contribution can reasonably be determined to occur and the time periods within which the first symptom or manifestation of illness or condition can reasonably be determined to occur after vaccination.

RECORDING AND REPORTING OF INFORMATION

The bill provides that each health care provider who administers a childhood vaccine shall record or insure that there is recorded the date of administration of the childhood vaccine, the manufacture and lot number of the vaccine, and any other identifying information on the childhood vaccine which may be required pursuant to regulations issued by the Secretary. This provision is predicated on testimony from parents who believe that their children were injured by a childhood vaccine but encountered difficulty in securing information regarding their child's immunization. The Committee notes that written proof of a child's immunization against childhood diseases is required by most states prior to entry to school. The Committee believes such essential information about a child's immunizations should be kept a part of their permanent medical record.

The bill also requires health providers and vaccine manufacturers to report to the Secretary of Health and Human Services, information about any complication or adverse reaction to a childhood vaccine. The Committee heard testimony regarding the deficiencies in the current system of reporting adverse reactions to childhood vaccines. Dr. William Foege, testifying for the Centers for Disease Control, stated that the current monitoring system is not designed to provide exact information about the rates of adverse events following vaccination. It does not involve systematic follow-up of all vaccine recipients to inquire whether they have had an adverse event, and it affects only vaccines administered in the public sector, which account for approximately one-half of all vaccines. The Committee notes that the primary use of the current reporting

system is to provide an indication of clustering of events or of the occurrence of unusual and previously unrecognized events. The Committee also notes that the Food and Drug Administration is in the process of developing regulations that would make reporting of adverse reactions to biologics mandatory for manufacturers.

The current system is voluntary and passive and depends upon the willingness of private physicians to report adverse reactions to childhood vaccines. In the case of vaccines administered in the public health clinics, the reporting is dependent upon the parent or guardian reading, understanding, and remembering to monitor the reactions listed on the "Important Information" forms they are given at the public health clinics. The Institute of Medicine in its publication, "Vaccine Supply and Innovation," noted that although these existing systems are useful, neither of them provides an adequate basis for estimating the total number of events that occur, in part because the reporting is voluntary. The lack of accurate statistical information on the adverse reactions associated with childhood vaccines may affect the ability of the Secretary to make accurate recommendations on the contraindications for childhood vaccines. The deficiencies in the passive, voluntary system of reporting adverse reactions has also diminished the faith many parents have in the nation's childhood immunization effort.

The Committee realizes that many health practitioners may be reluctant to report an adverse childhood vaccine reaction fearing that it might be construed as an admission of liability. The Committee therefore has added a provision which specifically states that such compliance shall not be admitted in evidence for the purpose of establishing culpability of the health care provider in any civil action in tort. The bill does not preclude the introduction of such information into evidence during a civil action in tort, it merely prevents it from being used to establish culpability.

The Committee notes that the Food and Drug Administration requires the manufacturers or childhood vaccines to report to it certain adverse reactions. The Committee wishes to avoid a duplication of effort, and therefore has added language in Section 2107 that will permit the Secretary to develop regulations to coordinate efforts of different agencies and ensure that the Centers of Disease Control receives all reports of suspected adverse reactions. However, the Committee notes that the two public health agencies collect different types of data for different purposes. The adverse reactions that are reported to the FDA are primarily designed to monitor and avoid "hot lots" of vaccines which may have to recalled in order to protect the public health. Therefore, the FDA does not require reporting of all noted adverse reactions, but only what the vaccine manufacturers believe to be significant adverse reactions. The vaccine manufacturers do not report all reactions reported to them if the reactions is considered minor or insignificant. The reports to the Congress for Disease Control are meant to establish a statistical record by which researchers can determine if a child who has suffered a minor reaction to a childhood vaccine is more or less likely to suffer a serious reaction to that same vaccine.

The Committee believes that information regarding the adverse reactions to childhood vaccines including locality and State of immunization, date of the vaccination, information concerning report-

ed symptoms, manifestation of resulting illness, disability, or injury and name of the health care provider should be a matter of public record. But the Committee does not believe that the name of the individual who suffered an adverse reaction need be available to the public and the bill contains a prohibition against releasing information which may identify the individual to the general public.

RULES WITH RESPECT TO CHILDHOOD VACCINE ADMINISTRATION

After the Secretary receives the report and recommendations of the Advisory Committee in respect to recommendations regarding the administration of childhood vaccines, the Secretary shall institute a rulemaking proceeding before publishing the Secretary's recommendations regarding circumstances which warrant delayed administration of childhood vaccines and the groups, categories or characteristics of potential recipients who may be at significantly higher risk of adverse reactions than the general population.

The Committee intends that this information and the recommendations be made available to health care providers who administer childhood vaccines. Therefore, the Committee has required that the Secretary go beyond the normal procedure of publishing the recommendations in the Federal Register and take appropriate steps to insure that the information is widely disseminated to physicians and other health care providers, professional health associations; State and local governments and health agencies and the other relevant entities.

PARENT INFORMATION

Until safer childhood vaccines are developed, licensed and available in the United States, the primary method of reducing adverse reactions to children is through an informed public. The Committee notes that several provisions in this bill are designed to widen the knowledge about adverse reactions to childhood vaccines, categories of individuals who might be particularly susceptible to serious adverse reactions, conditions, and about illnesses and diseases which might be causally related to childhood vaccines. The Committee feels that it is essential that this information be communicated to parents. Parents and guardians of children who are receiving these immunizations are in the best position to monitor their childrens' reactions to the immunization. These parents need to know what types of information should be communicated to the health care provider and what types of reactions to monitor.

The Committee feels it essential that the development of these parent information materials be made with the advice, counsel and cooperation of parents. The Committee notes that the inadequacy of the current "Important Information" forms has been noted by several sessions of the Annual Immunization Conference. The Centers for Disease Control has undertaken efforts to improve these forms and the Committee also acknowledges the efforts of the American Academy of Pediatricians to provide parents with understandable information about possible adverse reactions to childhood vaccines. The Committee commends these steps but it envisions now a more broad-based information effort. Further the Committee

is concerned over a study indicating that most parents do not read or understand the materials they receive at public health clinics.

The bill requires that these parent information materials be developed after notice to the public and an opportunity for a public hearing, and in consultation with the Advisory Commission, appropriate health care providers, the FDA, the CDC and parent organizations.

MANDATE FOR SAFER CHILDHOOD VACCINES

The Secretary is directed to promote the development or refinement of childhood vaccines that result in fewer and less serious adverse reactions and use all the power and authority of the Secretary's office to reduce the risks of adverse reactions to childhood vaccines. The Committee does not feel that a statement that the benefits of immunization outweigh the risks is satisfactory response to the need for safer childhood vaccines. The Committee directs the Secretary to take appropriate steps to promote the development of safer childhood vaccines and reduce the number of adverse reactions to current vaccines.

The Committee notes that many current vaccines, expecially the killed viral and bacterial vaccines, contain superfluous materials that may contribute to reactivity and that are irrelevant to the development of immunity. It is hoped that through further research, we may soom have the capability to replace existing vaccines with specific antigens that are more efficacious, safer and possibly less expensive. The Committee notes the research breakthroughs in the areas of recombinant DNA techniques, polypeptide synthesis, specific attenuation of pathogens, and anti-idiotype antibodies and is encouraged that the prospects for new and better vaccines are considerable.

However, the Committee notes that the development of these better vaccines may be impeded by economic disincentives to innovation and production, factors influencing the market for vaccines, vaccine utilization, and provider and client factors. The Committee is concerned that after vaccines first succeed in drastically reducing their target diseases, resources are often diverted to other pressing disease problems, with the result that the knowledge base needed to develop subsequent safer vaccines is often lost. Thus, the Committee hopes that these amendments will prompt a new level of commitment to improved vaccines and practice in vaccine therapy, from research through administration to monitoring.

RESEARCH FOR A SAFER PERTUSSIS VACCINE

The Committee is concerned that the public's confidence in the pertussis vaccine is waning. In the mid-1970's, injuries related to the DPT vaccine became a major public health issue in Japan, Sweden, and the United Kingdom. This concern over the adverse reactions associated with the DPT vaccine affected the public's willingness to have children vaccinated and resulted in resurgence of the disease. The Committee agrees with a study issued by the Institute of Medicine which concluded that while the health benefits of an improved pertussis vaccine may be small compared with those of new vaccines, a pertussis improvement project deserves

immediate attention for humanitarian and public policy reasons. S. 827 therefore authorizes additional funding for research specifically targeted on studies to identify and develop improved, safe and effective pertussis vaccines.

The Committee is aware that an accellular vaccine developed in Japan has been tested for safety in limited populations of U.S. children and is currently being tested for efficacy in a large controlled trial in Sweden. This trial is being supported by funding from the National Institute of Allergy and Infectious Diseases. The Committee also notes that the Senate Appropriations Committee has increased the NIAID intramural research budget, with directions that a portion of those funds be used to intensify research efforts to develop a highly purified pertussis vaccine using recombinant DNA technology. This effort has the Committee's full support.

REPORTS RELATING TO CHILDHOOD VACCINES

In order to improve the statistical data regarding adverse reactions to childhood vaccines, the bill requires vaccine manufacturers to report to the Centers for Disease Control adverse reactions that come to their attention. The Committee notes that vaccine manufacturers already must report known adverse reactions to the Food and Drug Administration. The Committee feels that these two public health agencies serve different functions and in some cases require different information. Therefore, the Committee has included in S. 827, a provision which permits the Secretary to take appropriate actions to coordinate the receipt, collection and evaluation of reports submitted to CDC and FDA in order to reduce duplication and ensure that all reports are received by the Centers for Disease Control.

RECALL AUTHORITY

The bill authorizes the Food and Drug Administration to recall any childhood vaccine upon a determination that a batch, lot or other portion of licensed product presents an imminent hazard to public health. The bill provides for a civil penalty of up to $100,000 per day of a violation of the recall order. In implementing this provision the Committee intends that the Secretary refer to the definitions and regulations currently promulgated under imminent hazard authorities already contained in the Food, Drug and Cosmetic Act.

AUTHORIZATION FOR IMMUNIZATION PROGRAM

The authority for the state grants for childhood vaccines is increased from $65,000,000 to $90,000,000 for Fiscal Year 1987. The Committee notes that the increase in federal funding for state grants for childhood immunization is compelled by the price increases by vaccine manufacturers who are either self-insuring or attempting to reserve funds for possible lawsuits.

STOCKPILE

Each of the major pediatric vaccines used in the United States is now supplied by one or at most two distributors. Of the three com-

mercial firms marketing DPT, one has ceased distribution of the vaccine and the remaining two have experienced difficulty in obtaining insurance coverage. In December 14, 1984, the Centers for Disease Control announced that a DPT shortage would occur beginning in 1985. The existing supply disruption resulted in short-term shortages, rationing, and the postponement of needed important vaccine inoculations. The Committee notes that the CDC requested funds to establish a 6 month stockpile of vaccines in 1982. The following year $4.57 million was allotted for this purpose. In 1984, the CDC requested $20.5 million for stockpiling. That request was reduced to $8 million by the Public Health Service and $4 million by the Office of Management and Budget. These figures proved inadequate. The Committee notes that because of the tremendous increases in the price of the vaccine over the last few years, the lack of sufficient funding during these years for a stockpile not only contributed to the supply shortfall which occurred in 1985, but also increased the cost of the stockpile, which now must include larger quantities of the later, far more expensive, vaccines.

VI. Votes in Committee

S. 827 was brought up for markup at the Committee Executive session on July 30, 1986. At that time Senator Hawkins offered an amendment in the nature of a substitute which was accepted and ordered reported favorably from Committee unanimously by voice vote.

VII. Cost Estimate

U.S. Congress,
Congressional Budget Office,
Washington, DC, August 28, 1986.

Hon. Orrin G. Hatch,
Chairman, Committee on Labor and Human Resources,
U.S. Senate, Washington, DC.

Dear Mr. Chairman: The Congressional Budget Office has prepared the attached cost estimate for S. 827, the National Childhood Vaccine Improvement Act of 1986, as ordered reported by the Senate Committee on Labor and Human Resources on August 6, 1986.

If you wish further details on this estimate we will be pleased to provide them.

With best wishes,
Sincerely,

Edward Gramlich
(For Rudolph G. Penner, Director).

CONGRESSIONAL BUDGET OFFICE COST ESTIMATE

1. Bill number: S. 827.

2. Bill title: National Childhood Vaccine Improvement Act of 1986.

3. Bill status: As ordered reported by the Senate Committee on Labor and Human Resources on August 6, 1986.

4. Bill purpose: To create incentives to reduce risks assocated with childhood vaccines and to promote the development and dissemination to parents of information on the risks and benefits of childhood vaccines.

5. Estimated cost to the Federal Government:

[By fiscal year, in million of dollars]

	1987	1988	1989	1990	1991
Estimated authorization level:					
Advisory Commission	1.0	1.0	1.0	1.0	1.0
Study	.8	.9	.9		
Reporting to CDC and FDA	.4	.4	.4	.4	.4
Parent information	1.0	1.0	1.0	1.0	1.0
Research	11.0	1.0			
Immunization grants	25.0				
Vaccine stockpile	7.4	7.4	7.4		
Total estimated authorization level	46.6	11.7	10.7	2.4	2.4
Total estimated outlays	34.4	18.7	14.7	3.6	2.4

Basis of Estimate

The authorization levels for research on pertussis vaccines and for the immunization program are stated in the bill. All other authorization levels are estimated. We assume all authorized amounts are fully appropriated at the beginning of each fiscal year. Outlays are estimated using spendout rates calculated by CBO on the basis of similar program data. All authorizations are subject to subsequent appropriations action.

The bill would establish an Advisory Commission on Childhood Vaccines. The Commission would be responsible for several scientific studies and surveys. The bill does not authorize a specific number of members for the Commission or number of support staff. For this estimate, we assume 10 Commission members would be appointed with a full-time staff of 10. Salary and overhead is estimated to be about $1 million in each fiscal year. Costs could be higher or lower depending on the actual number of Commission members and staff appointed. The Commission would be required to report within three years whether or not a causal relationship exists between pertussis vaccines, measels, mumps and rubella vaccines, and certain illnesses. CBO expects this study to cost about $2.5 million over three years.

The bill would make it mandatory for physicians and vaccine manufacturers to report adverse reactions to the Centers for Disease Control (CDC) and the Food and Drug Administration (FDA) respectively. Both agencies currently collect some of this information, but expect this provision would increase their workloads. CBO estimates additional personnel would be needed at CDC and FDA to process the additional reports at a total cost of about $400,000 each year.

The bill would require the Secretary of Health and Human Services to provide information to parents on adverse reactions to be distributed by health care providers administering vaccines. The

development, printing and dissemination costs for these materials are expected to be about $1 million each year.

The bill would require CDC to maintain a vaccine stockpile sufficient to provide vaccinations over a six-month period. CDC is currently working toward this goal and estimates it would require an additional $22.2 million to complete their six-month stockpile. CDC currently receives about $4 million each year specifically for augmenting the vaccine stockpile. They believe they could purchase about $6 million to $8 million worth of vaccines each year without placing a supply burden on manufacturers. Accordingly, CBO has estimated that just over $7 million would be provided for the vaccine stockpile for each of the next three years.

6. Estimated cost to State and local government: The budgets of state and local governments would not be affected directly by enactment of this legislation.

7. Estimate comparison: None.

8. Previous CBO estimate: None.

9. Estimate prepared by: Carmela Dyer.

10. Estimate approved by: C.G. Nuckols (for James L. Blum, Assistant Director for Budget Analysis).

VIII. Regulatory Impact Statement

Pursuant to Section 602 of Senate Resolution 4 concerning the regulatory impact of proposed legislation, the Committee has determined that the provisions requiring mandatory recordkeeping of childhood immunizations by health care providers and mandatory reporting of known adverse reactions to childhood vaccines by both health providers and vaccine manufacturers will result in a minimal increase in regulatory burden or paperwork imposed by the bill.

IX. Family Fairness Statement

The Committee has determined that passage of S. 827 as reported from Committee will have a positive impact upon families. In assisting the development of safer chidhood vaccines, helping prevent neddless adverse reactions through public education programs, and through the establishment of a six-month vaccine stockpile against the temporary shortages, the bill will help save childrens' lives and minimize injuries which are to be anticipated under our current childhood immunization programs.

X. Section-by-Section Analysis

Section 1 of the bill cites the Act as the "National Childhood Vaccine Improvement Act of 1986" and displays the table of contents.

Section 2 of the bill sets forth Congressional findings about childhood vaccinations: (1) Cooperation between the Federal Government and the States has resulted in mandatory preschool vaccination laws; (2) While the childhood vaccination programs have been successful in reducing diseases, an unknown number of persons have been injured as a result of the inoculations; (3) Because the vaccination programs and their potential problems are of both Fed-

eral and national concern, there is a need to establish a system to encourage the production of the safest possible childhood vaccines. The section also sets forth the purposes of the new title: (1) to establish mechanisms and create incentives to reduce the risks associated with presently available childhood vaccines; and (2) to promote the development and dissemination to parents of information on vaccines risks and benefits.

Section 3 of the bill amends the Public Health Service Act by creating a new Title XXI—Assuring a Safer Childhood Vaccination Program in the United States. Sections 2101 through 2115 of old Title XXI—Miscellaneous are redesignated as sections 3 through 15 under Title I—General Provisions.

The new Title XXI has the following sections:

Section 2101 establishes the Advisory Commission on Childhood Vaccines.

Subsection 2101(a) describes the membership of the Commission, including at least one representative from each of the following groups: (1) a physician, vaccine researcher, or vaccine manufacturer; (2) a member of a concerned parents group; and (3) a representative of State or local health agencies or public health organizations.

Subsection 2101(b) directs that the Commission first meet within 30 days of the appointment of all its members, and thereafter at least three times per year.

Subsection 2101(c) defines the pay and reimbursement schedules applicable to members of the Commission.

Subsection 2101(d) provides for an Executive Director and professional and clerical staff for the Commission.

Subsection 2101(e) instructs the Commission to: (1) study and recommend ways to ensure the availability, safety, and efficacy of childhood vaccines; (2) survey and analyze existing programs for vaccine injury reporting, and advise the Secretary on means to obtain, compile, publish, and use credible data on the frequency and severity of adverse reactions to childhood vaccines; and (3) recommend research priorities to enhance the safety and efficacy of vaccines.

Subsection 2101(f) directs the Commission to complete within three years a review of medical and scientific information on any relationships between vaccines containing pertussis and a number of specific diseases and conditions. The Commission is also to review the potential relationship between radiculoneuritis, and MMR and other vaccines containing rubella. The reviews must include opportunity for public hearing and comments. Within three years, the Commission must report the findings of these reviews. It must report whether the various illnesses listed can in some circumstances be caused or contributed to by the pertussis or rubella vaccines. In each case in which a relationship is found between an illness or condition and the pertussis vaccine, the report must describe the probable circumstances of such an occurrence and the likely time frame within which symptoms would appear.

Subsection 2101(g) provides that within one year the Commission shall conduct and support a broad study of the risks to children associated with each childhood vaccine, and make recommendations to the Secretary concerning contraindications to vaccine adminis-

tration. The recommendations must address the circumstances under which a vaccine should not be administered, those under which administration should be delayed, and the characteristics of any groups of children who are at significantly higher risk of major adverse reactions to vaccines than the general population.

Subsection 2101(h) provides authorization of such sums as may be necessary for the activities of the Commission for each of the fiscal years 1987 through 1991.

Section 2102 addresses recording and reporting of information.

Subsection 2102(a) requires that each time a childhood vaccine is administered, the health care provider must keep a record of the date, the manufacturer and lot number of the vaccine, the name of the person giving the inoculation, and any other required information.

Subsection 2102(b) sets forth reporting requirements for any health care provider who, after administering a childhood vaccine, becomes aware that the recipient has suffered a complication of immunization. The health care provider must report to the Centers for Disease Control the occurrence of the complication, and provide relevant information including the type of vaccine, the time elapsed from administration of the vaccine to occurrence of the complication, the manufacturer and lot number of the vaccine, and the other information required in subsection (a) above. If the complication occurs within 30 days after administration of the vaccine, and if the health care provider receives oral or written notification or otherwise becomes aware of the complication, the provider must record the symptoms and other information about the complication in the recipient's permanent medical record. In addition, if a health care provider or vaccine manufacturer becomes aware of any illness, disability, injury, or condition that may possibly be related to the administration of a childhood vaccine, the provider or manufacturer must report the occurrence of the possible complication to the Secretary.

Subsection 2102(c) provides that information which is in the possession of Federal, State, or local governments under this section and which might identify an individual may not be made available under the Freedom of Information Act (5 U.S.C. 552) to anyone other than the recipient of the childhood vaccine or the recipient's parent, legal guardian, or authorized legal representative. Information thus protected is limited to the name, street address, telephone number, and actual medical records of the vaccine recipient, and of the parent or guardian; information not protected from disclosure includes the locality and State of inoculation, the name of the health care provider administering the vaccine, the date of the vaccination, and information concerning any reported complications. Except for the identifying information described above, all information reported under this section shall be available to the public.

Subsection 2102(d) provides that compliance by a physician or other health care provider with the requirements of this section shall not be construed as an admission of liability, and the fact of such compliance shall not be admitted in evidence in any tort action brought against the provider. The content of the recorded or reported information, however, may be admitted in evidence with

the permission of the person about whom the record or report was made.

Section 2103 provides for promulgation by the Secretary of rules with respect to childhood vaccine administration. After receiving and considering the recommendations of the Commission under section 2101(g), the Secretary shall specify: (1) the circumstances under which any childhood vaccine should not be administered; (2) the circumstances under which administration of a vaccine should be delayed; and (3) the groups, categories, or characteristics of potential vaccine recipients who may be at significantly higher risk of major adverse reaction to a vaccine than the general population of potential recipients. At least every three years, the Secretary shall review the vaccine administration rule and revise it as necessary, or else publish a finding in the Federal Register that no revision is warranted. The Secretary shall widely disseminate the information contained or referenced in the rule to physicians and other health care providers, professional health associations, State and local governments and agencies, and other relevant entities.

Section 2104 requires the Secretary within one year to develop parent information materials for distribution by health care providers to the parents or guardians of any child receiving a childhood vaccine. The materials are to be developed with opportunity for public comment, and in consultation with the Commission, health care providers and parent organizations, the Food and Drug Administration, and the Centers for Disease Control. Information to be covered includes: (1) the frequency, severity, and potential long-term effects of the disease to be prevented by the vaccine; (2) vaccine reactions that should be brought to the immediate attention of the health care provider; (3) precautionary measures parents should take to reduce the risk of any major adverse reactions to the vaccine; (4) early warning signs or symptoms to which parents should be alert as possible precursors to major adverse reactions; (5) information on how parents should monitor any major adverse reactions, including a form for reporting reactions; (6) a specification of when, how, and to whom parents may report any major adverse reactions; (7) the contra-indications to (and bases for delay of) the administration of the vaccine; (8) an identification of the characteristics of groups of children who may be at significantly higher risk of major adverse vaccine reactions than the general population; (9) a summary of any relevant State and Federal laws concerning the vaccine, including requirements for school attendance and the recommended vaccination schedule; (10) any other relevant information as may be determined by the Secretary.

Section 2105 gives the Secretary a mandate to promote the development or refinement of childhood vaccines that result in fewer and less serious adverse reactions. The Secretary is directed to oversee improvements in all phases of vaccine manufacturing, testing, labeling, use, reporting, recall, and research in order to reduce the risks of adverse reactions, and to report on these activities to Congress every two years. Within one year, the Secretary must review all the warnings, use instructions, and precautionary information presently issued by manufacturers of the seven required childhood vaccines, and determine whether the information adequately warns health care providers of the potential risks of the

vaccines. If the warnings are deemed inadequate, the manufacturers will be required to revise them expeditiously.

Section 2106 directs the Secretary to conduct research on new, safe, and effective pertussis vaccines, including the sponsorship of laboratory studies of the immune response to, and diagnosis of, pertussis; phase I safety and immunogenicity studies; field trials of the safety and efficacy of new pertussis vaccines; and epidemiologic studies of the incidence of serious reactions to the new vaccines. Appropriatios for this research are authorized at $11,000,000 for FY 1987 and $1,000,000 for FY 1988.

Section 2107 concerns records and reports relating to childhood vaccines.

Subsection 2107(a) addresses the responsibility of vaccine manufacturers to maintain records and make reports. It makes the provisions of section 505(k) of the Federal Food Drug, and Cosmetic Act applicable to childhood vaccine manufacturers licensed under section 351 of the Public Health Service Act. Under section 505(k), manufacturers are required to maintain records, and make reports to the Secretary, of "data relating to clinical experience" with their products, and such other information as the Secretary may prescribe.

Subsection 2107(b) provides that the Secretary take appropriate actions to coordinate the receipt, collection, and evaluation of the various reports on vaccine reactions (those submitted to the Centers for Disease Control under section 2102 and those submitted to the Food and Drug Administration under this section). The aim of this coordination is to avoid, insofar as practicable, duplicate reporting of the same events resulting from the administration of vaccines, and to ensure that all such reports are available for evaluation by the Centers for Disease Control.

Section 2108 provides definitions of the terms "Commission", "childhood vaccine", "health provider", "medical and scientific information", "MMR" (the immunization combining the measles, mumps, and rubella vaccines), and "vaccine manufacturer."

Section 2109 is a severability provision, stating that in the event any portion of this title is declared unconstitutional or invalid, the rest of the title shall remain unaffected and in force.

Section 4 of the bill makes technical amendments to three sections of the Public Health Service Act.

Section 5 of the bill amends the Public Health Service Act by adding a new paragraph about recall authority to section 351(d), which concerns licensing of manufacturers of biological products. The new paragraph gives the Secretary authority to order the immediate recall of any batch, lot, or other portion of a biological product that has been determined to present an imminent hazard to the public health. Any violation of such a recall order shall subject the violator to a civil penalty of up to $100,000 per day of violation.

Section 6 of the bill increases the authorization of appropriations for FY 1987 for immunization programs by striking out "$65,000,000" in section 317(j)(1) of the Public Health Service Act and inserting "$90,000,000."

Section 7 of the bill requires the Secretary, through the Centers for Disease Control, to acquire and maintain a stockpile of vaccines sufficient to last six months.

XI. Changes in Existing Law

In compliance with rule XXVI paragraph 12 of the Standing Rules of the Senate, the following provides a print of the statute or the part or section thereof to be amended, or replaced (existing law proposed to be omitted is enclosed in black brackets, new matter is printed in italic, existing law in which no change is proposed is shown in roman):

Public Health Service Act

[TITLE I—SHORT TITLE AND DEFINITIONS]

TITLE I—GENERAL PROVISIONS

SHORT TITLE

Section 1. This act may be cited as the "Public Health Service Act".

DEFINITIONS

Sec. 2. When used in this Act—

(a) The term "Service" means the Public Health Service;

(b) The term "Surgeon General" means the Surgeon General of the Public Health Service;

(c) Unless the context otherwise requires, the term "Secretary" means the Secretary of Health, Education, and Welfare;

(d) The term "regulations", except when otherwise specified, means rules and regulations made by the Surgeon General with the approval of the Secretary;

(e) The term "executive department" means any executive department, agency, or independent establishment of the United States or any corporation wholly owned by the United States;

(f) Except as provided in sections 314(g)(4)(B), 318(c)(1), 331(h)(3), 335(5), 361(d), 701(9), 1002(c), 1401(13), 1531(1), and 1633(1), the term "State" includes, in addition to the several States, only the District of Columbia, Guam, the Commonwealth of Puerto Rico, the Northern Mariana Islands, the Virgin Islands, American Samoa, and the Trust Territory of the Pacific Islands.

(g) The term "possession" includes, among other possessions, Puerto Rico and the Virgin Islands;

(h) [Repealed.]

(i) The term "vessel" includes every description of watercraft or other artificial contrivance used, or capable of being used, as a means of transportation on water, exclusive of aircraft and amphibious contrivances;

(j) The term "habit-forming narcotic drug" or "narcotic" means opium and coca leaves and the several alkaloids derived therefrom, the best known of these alkaloids being morphia, heroin, and codeine, obtained from opium, and cocaine derived from the coca plant; all compounds, salts, preparations, or other derivatives ob-

tained from the raw material or from the various alkaloids; Indian hemp and its various derivatives, compounds, and preparations, and peyote in its various forms; isonipecaine and its derivatives, compounds, salts and preparations; opiates (as defined in section 3228(f) of the Internal Revenue Code);

(k) The term "addict" means any person who habitually uses any habit-forming narcotic drugs so as to endanger the public morals, health, safety, or welfare, or who is or has been so far addicted to the use of such habit-forming narcotic drugs as to have lost the power of self-control with reference to his addiction;

(l) The term "psychiatric disorders" includes diseases of the nervous system which affect mental health;

(m) The term "State mental health authority" means the State health authority, except that, in the case of any State in which there is a single State agency, other than the State health authority, charged with responsibility of administering the mental health program of the State, it means such other State agency;

(n) The term "heart diseases" means diseases of the heart and circulation;

(o) The term "dental diseases and conditions" means diseases and conditions affecting teeth and their supporting structures, and other related diseases of the mouth;

(p) The term "uniformed service" means the Army, Navy, Air Force, Marine Corps, Coast Guard, Public Health Service, or Coast and Geodetic Survey; and

(q) The term "drug dependent person" means a person who is using a controlled substance (as defined in section 102 of the Controlled Substance Act) and who is in a state of psychic or physical dependence, or both, arising from the use of that substance on a continuous basis. Drug dependence is characterized by behavioral and other responses which include a strong compulsion to take the substance on a continuous basis in order to experience its psychic effects or to avoid the discomfort caused by its absence.

[TITLE XXI—MISCELLANEOUS]

GIFTS

SEC. [2101.] *3.* (a) The Secretary is authorized to accept on behalf of the United States gifts made unconditionally by will or otherwise for the benefit of the Service or for the carrying out of any of its functions. Conditional gifts may be so accepted if recommended by the Surgeon General, and the principal of and income from any such conditional gift shall be held, invested, reinvested, and used in accordance with its conditions, but no gift shall be accepted which is conditioned upon any expenditure not to be met therefrom or from the income thereof unless such expenditure has been approved by Act of Congress.

(b) Any unconditional gift of money accepted, pursuant to the authority granted in subsection (a) of this section, the net proceeds from the liquidation (pursuant to subsection (c) or subsection (d) of this section) of any other property so accepted, and the proceeds of insurance on any such gift property not used for its restoration, shall be deposited in the Treasury of the United States and are

hereby appropriated and shall be held in trust by the Secretary of the Treasury for the benefit of the Service, and he may invest and reinvest such funds in interest-bearing obligations of the United States or in obligations guaranteed as to both principal and interest by the United States. Such gifts and the income from such investments shall be available for expenditure in the operation of the Service and the performance of its functions, subject to the same examination and audit as is provided for appropriations made for the Service by Congress.

(c) The evidences of any unconditional gift of intangible personal property, other than money, accepted pursuant to the authority granted in subsection (a) of this section shall be deposited with the Secretary of the Treasury and he, in his discretion, may hold them, or liquidate them except that they shall be liquidated upon the request of the Secretary, whenever necessary to meet payments required in the operation of the Service or the performance of its functions. The proceeds and income from any such property held by the Secretary of the Treasury shall be available for expenditure as is provided in subsection (b) of this section.

(d) The Secretary shall hold any real property or any tangible personal property accepted unconditionally pursuant to the authority granted in subsection (a) of this section and he shall permit such property to be used for the operation of the Service and the performance of its functions or he may lease or hire such property, and may insure such property, and deposit the income thereof with the Secretary of the Treasury to be available for expenditure as provided in subsection (b) of this section: *Provided,* That the income from any such real property or tangibele personal property shall be available for expenditure in the discretion of the Secretary for the maintenance, preservation, or repair and insurance of such property and that any proceeds from insurance may be used to restore the property insured. Any such property when not required for the operation of the Service or the performance of its functions may be liquidated by the Secretary, and the proceeds thereof deposited with the Secretary of the Treasury, whenever in his judgment the purposes of the gifts will be served thereby.

USE OF IMMIGRATION STATION HOSPITALS

SEC. [2102.] *4.* The Immigration and Naturalization Service may, by agreement of the heads of the departments concerned, permit the Public Health Service to use hospitals at immigration stations for the care of Public Health Service patients. The Surgeon General shall reimburse the Immigration and Naturalization Service for the actual cost of furnishing fuel, light, water, telephone, and similar supplies and services, which reimbursement shall be covered into the proper Immigration and Naturalization Service appropriation, or such costs may be paid from working funds established as provided by law, but no charge shall be made for the expense of physical upkeep of the hospitals. The Immigration and Naturalization Service shall reimburse the Surgeon General for the care and treatment of persons detained in hospitals of the Public Health Service at the request of the Immigration and

Naturalization Service unless such persons are entitled to care and treatment under section 322(a).

MONEY COLLECTED FOR CARE OF PATIENTS

SEC. [2103.] *5.* Money collected as provided by law for expenses incurred in the care and treatment of foreign seamen, and money received for the care and treatment of pay patients, including any amounts received from any executive department on account of care and treatment of pay patients, shall be covered into the appropriation from which the expenses of such care and treatment were paid.

TRANSPORTATION OF REMAINS OF OFFICERS

SEC. [2106.] *6.* Appropriations available for traveling expenses of the Service shall be available for meeting the cost of preparation for burial and of transportation to the place of burial of remains of commissioned officers, and of personnel specified in regulations, who die in line of duty. Appropriations available for carrying out the provisions of this Act shall also be available for the payment of such expenses relating to the recovery, care, and disposition of the remains of personnel or their dependents as may be authorized under other provisions of law.

GRANTS TO FEDERAL INSTITUTIONS

SEC. [2107.] *7.* Appropriations to the Public Health Service available under this Act for research, training, or demonstration project grants or for grants to expand existing treatment and research programs and facilities for alcoholism, narcotic addiction, drug abuse, and drug dependence and appropriations under title VI of the Mental Health Systems Act shall also be available, on the same terms and conditions as apply to non-Federal institutions, for grants for the same purpose to Federal institutions, except that grants to such Federal institutions may be funded at 100 per centum of the costs.

TRANSFER OF FUNDS

SEC. [2108.] *8.* For the purpose of any reorganization under section 202, the Secretary, with the approval of the Director of the Bureau of the Budget, is authorized to make such transfers of funds between appropriations as may be necessary for the continuance of transferred functions.

AVAILABILITY OF APPROPRIATIONS

SEC. [2109.] *9.* Appropriations for carrying out the purposes of this Act shall be available for expenditure for personal services and rent at the seat of Government; books of reference, periodicals, and exhibits; printing and binding; transporting in Government-owned automotive equipment, to and from school, children of personnel who have quarters for themselves and their families at stations determined by the Surgeon General to be isolated stations; expenses incurred in pursuing, identifying, and returning prisoners who escape from any hospital, institution, or station of the Service or

from the custody of any officer or employee of the Service, including rewards for the capture of such prisoners; furnishing, repairing, and cleaning such wearing apparel as may be prescribed by the Surgeon General for use by employees in the performance of their official duties; reimbursing officers and employees, subject to regulations of the Secretary, for the cost of repairing or replacing their personal belongings damaged or destroyed by patients while such officers or employees are engaged in the performance of their official duties; and maintenance of buildings of the National Institutes of Health.

UNAUTHORIZED WEARING OF UNIFORMS

SEC. [2110.] *10.* Except as may be authorized by regulations of the President, the insignia and uniform of commissioned officers of the Service, or any distinctive part of such insignia or uniform, or any insignia or uniform any part of which is similar to a distinctive part thereof, shall not be worn, after the promulgation of such regulations, by any person other than a commissioned officer of the Service.

ANNUAL REPORT

SEC. [2111.] *11.* The Surgeon General shall tramsmit to the Secretary, for submission to the Congress at the beginning of each regular session, a full report of the administration of the functions of the Service under this Act, including a detailed statement of receipts and disbursements.

MEMORIALS AND OTHER ACKNOWLEDGMENTS

SEC. [2112.] *12.* The Secretary may provide for suitably acknowledging, within the Department (whether by memorials, designation, or other suitable acknowledgments), (1) efforts of persons who have contributed substantially to the health of the Nation and (2) gifts for use in activities of the Department related to health.

EVALUATION OF PROGRAMS

SEC. [2113.] *13.* Such portion as the Secretary may determine, but not more than 1 per centum, of any appropriation for grants, contracts, or other payments under any provision of this Act, the Mental Health Systems Act, the Act of August 5, 1954 (Public Law 568, Eighty-third Congress), or the Act of August 16, 1957 (Public Law 85–151), for any fiscal year beginning after June 30, 1970, shall be available for evaluation (directly, or by grants or contracts) of any program authorized by this Act or any of such other Acts, and, in the case of allotments from any such appropriation, the amount available for allotment shall be reduced accordingly.

CONTRACT AUTHORITY

SEC. [2114.] *14.* The authority of the Secretary to enter into contracts under this Act shall be effective for any fiscal year only to such extent or in such amounts as are provided in advance by appropriation Acts.

RECOVERY

SEC. [2115.] *15.* (a) If any facility with respect to which funds have been paid under the Community Mental Health Centers Act (as such Act ws in effect prior to October 1, 1981) is, at any time within twenty years after the completion of remodeling, construction, or expansion or after the date of its acquisition—

(1) sold or transferred to any entity (A) which would not have been qualified to file an application under section 222 of such Act (as such section was in effect prior to October 1, 1981) or (B) which is disapproved as a transferee by the State mental health agency or by another entity designated by the chief executive officer of the State, or

(2) ceases to be used by a community mental health center in the provision of comprehensive mental health services,

the United States shall be entitled to recover from the transferor, transferee, or owner of the facility, the base amount prescribed by subsection (c)(1) plus the interest (if any) prescribed by subsection (c)(2).

(b) The transferor and transferee of a facility that is sold or transferred as described in subsection (a)(1), or the owner of a facility the use of which changes as described in subsection (a)(2), shall provide the Secretary written notice of such sale, transfer, or change within 10 days after the date on which such sale, transfer, or cessation of use occurs or within 30 days after the date of enactment of this subsection, whichever is later.

(c)(1) The base amount that the United States is entitled to recover under subsection (a) is the amount bearing the same ratio to the then value (as determined by the agreement of the parties or in an action brought in the district court of the United States for the district in which the facility is situated) of so much of the facility as constituted an approved project or projects as the amount of the Federal participation bore to the cost of the remodeling, construction, expansion, or acquisition of the project or projects.

(2)(A) The interest that the United States is entitled to recover under subsection (a) is the interest for the period (if any) described in subparagraph (B) at a rate (determined by the Secretary) based on the average of the bond equivalent rates of ninety-one-day Treasury bills auctioned during that period.

(B) The period referred to in subparagraph (A) is the period beginning—

(i) if notice is provided as prescribed by subsection (b), 191 days after the date on which such sale, transfer, or cessation of use occurs, or

(ii) if notice is not provided as prescribed by subsection (b), 11 days after such sale, transfer, or cessation of use occurs,

and ending on the date the amount the United States is entitled to recover is collected.

(d) The Secretary may waive the recovery rights of the United States under subsection (a)(2) with respect to a facility (under such conditions as the Secretary may establish by regulation) if the Secretary determines that there is good cause for waiving such rights.

(e) The right of recovery of the United States under subsection (a) shall not, prior to judgment, constitute a lien on any facility.

TITLE II—ADMINISTRATION

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NATIONAL ADVISORY COUNCILS

SEC. 217. (a) * * *

(b) The National Advisory Mental Health Council shall advise, consult with, and make recommendations to the Surgeon General on matters relating to the activities and functions of the Service in the field of mental health. The Council is authorized (1) to review research projects or programs submitted to or initiated by it in the field of mental health and recommend to the Surgeon General, for prosecution under this Act, any such projects which it believes show promise of making valuable contributions to human knowledge with respect to the cause, prevention, or methods of diagnosis and treatment of psychiatric disorders; and (2) to collect information as to studies being carried on in the field of mental health and, with the approval of the Surgeon General, make available such information through the appropriate publications for the benefit of health and welfare agencies or organizations (public and private), physicians, or any other scientists, and for the information of the general public. The council is also authorized to recommend to the Surgeon General, for acceptance pursuant to section [2101] *3* of this Act, conditional gifts for work in the field of mental health; and the Surgeon General shall recommend acceptances of any such gifts only after consultation with the Council.

(c) The National Advisory Council on Alcohol Abuse and Alcoholism shall advise, consult with, and make recommendations to, the Secretary on matters relating to the activities and functions of the Secretary in the field of alcohol abuse and alcoholism, including policies and priorities with respect to grants and contracts. The Council is authorized (1) to review research projects or programs submitted to or initiated by it in the field of alcohol abuse and alcoholism and recommend to the Secretary any such projects which it believes show promise of making valuable contributions to human knowledge with respect to the cause, prevention, or methods of diagnosis and treatment of alcohol abuse and alcoholism, and (2) to collect information as to studies being carried on in the field of alcohol abuse and alcoholism and, with the approval of the Secretary, make available such information through appropriate publications for the benefit of health and welfare agencies or organizations (public or private) or physicians or any other scientists, and for the information of the general public. The Council is also authorized to recommend to the Secretary, for acceptance pursuant to section [2101] *3* of this Act, conditional gifts for work in the field of alcohol abuse and alcoholism; and the Secretary shall recommend acceptance of any such gifts only after consultation with the Council.

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TITLE III—GENERAL POWERS AND DUTIES OF PUBLIC HEALTH SERVICE

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PART B—FEDERAL-STATE COOPERATION

SECS. 311–316. * * *

PROJECT GRANTS FOR PREVENTIVE HEALTH SERVICES

SEC. 317. (a)–(i) * * *

(j)(1) For grants under subsection (a) for preventive health service programs to immunize individuals against vaccine-preventable diseases there are authorized to be appropriated $29,500,000 for the fiscal year ending September 30, 1982, $32,000,000 for the fiscal year ending September 30, 1983, $34,500,000 for the fiscal year ending September 30, 1984, $52,000,000 for the fiscal year ending September 30, 1985, $59,000,000 for the fiscal year ending September 30, 1986, and [$65,000,000] *$90,000,000* for the fiscal year ending September 30, 1987.

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PART F—LICENSING—BIOLOGICAL PRODUCTS AND CLINICAL LABORATORIES AND CONTROL OF RADIATION

Subpart 1—Biological Products

REGULATION OF BIOLOGICAL PRODUCTS

SEC. 351. (a)–(c) * * *

(d)(1) Licenses for the maintenance of establishments for the propagation or manufacture and preparation of products described in subsection (a) of this section may be issued only upon a showing that the establishment and the products for which a license is desired meet standards, designed to insure the continued safety, purity, and potency of such products, prescribed in regulations, and licenses for new products may be issued only upon a showing that they meet such standards. All such licenses shall be issued, suspended, and revoked as prescribed by regulations and all licenses issued for the maintenance of establishment for the propagation or manufacture and preparation, in any foreign country, of any such products for sale, barter, or exchange in any State or possession shall be issued upon condition that the licensees will permit the inspection of their establishments in accordance with subsection (c) of this section.

(2)(A) Upon a determination that a batch, lot, or other portion of a product licensed under this section presents an imminent hazard to the public health, the Secretary shall, after opportunity for an expedited hearing, issue, in any case necessary to protect the public health, an order requiring the immediate recall of such batch, lot, or other portion of such product.

(B) Any violation of a recall order issued pursuant to subparagraph (A) shall subject the violator to a civil penalty of up to $100,000 per day of violation.

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TITLE IV—NATIONAL RESEARCH INSTITUTES

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PART D—NATIONAL LIBRARY OF MEDICINE

Subpart 1—General Provisions

PURPOSE, ESTABLISHMENT, AND FUNCTIONS OF THE NATIONAL LIBRARY OF MEDICINE

SEC. 465. (a)-(e) * * *

(f) Section [2101] *3* shall be applicable to the acceptance of administration of gifts made for the benefit of the Library or for carrying out any of its functions, and the Board of Regents shall make recommendations to the Secretary relating to establishment within the Library of suitable memorials to the donors.

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TITLE XXI—ASSURING A SAFER CHILDHOOD VACCINATION PROGRAM IN THE UNITED STATES

ADVISORY COMMISSION ON CHILDHOOD VACCINES

SEC. 2101. (a) There is established the advisory Commission on Childhood Vaccines. The members of the Commission shall be appointed by the Secretary, in consultation with the National Academy of Sciences. At least one member of the Commission shall be an individual who is engaged in vaccine research or in the manufacture of vaccines or who is a physician. At least one member of the Commission shall be an individual who is a member of an organization of parents concerned with vaccine immunizations. At least one member of the Commission shall be an individual who is a representative of State or local health agencies or public health organizations.

(b) The members of the Commission shall select a chairman from among the members. The Commission shall first meet within 30 days after all members of the commission are appointed, and thereafter shall meet at the call of the chairman, but not less often than three times per year.

(c) Members of the Commission who are officers or employees of the Federal Government shall serve as members of the Commission without compensation in addition to that received in their regular public employment. Members of the Commission who are not officers or employees of the Federal Government shall each receive the daily equivalent of the rate in effect for grade GS-18 of the General Schedule for each day (including traveltime) they are engaged in the performance of their duties as members of the Commission. All members, while so serving away from their homes or regular place of business, may be allowed travel expenses, including per diem in lieu of subsistence, in the same manner as such expenses are authorized by section 5703, title 5, United States Code, for employees serving intermittently.

(d) The Secretary shall—

(1) designate a senior member of the Secretary's staff to act as Executive Director of the Commission, and

(2) provide the Commission with such full-time professional and clerical staff, such information, and the services of such

consultants as may be necessary to assist the Commission in carrying out effectively its functions under this section.

(e) The Commission shall—

(1) study and recommend ways to encourage the availability of an adequate supply of safe and effective childhood vaccination products in the United States, with special emphasis on assisting the Secretary in implementing the Secretary's responsibilities under section 2105, regarding the need for childhood vaccination products that result in fewer or no significant adverse reactions;

(2) survey and analyze Federal, State, and local programs and activities relating to the gathering of information on injuries associated with the administration of childhood vaccines, including the adverse reaction reporting requirements of section 2102, and advise the Secretary on means to obtain, compile, publish, and use credible data related to the frequency and severity of adverse reactions associated with childhood vaccines;

(3) recommend research priorities and other measures the Secretary should take to enhance the safety and efficacy of childhood vaccines and to carry out this title; and

(4) carry out subsections (f) and (g).

(f)(1) Not later than 3 years after the date of enactment of this title, the Commission shall complete a review of all relevant medical and scientific information on—

(A) the nature, circumstances, and extent of the relationship, if any, between vaccines containing pertussic (including whole cell, extracts, and specific antigens) and hemolytic anemia, hypsarrhythmia, infantile spasms, Reye's syndrome, peripheral mononeuropathy, deaths classified as sudden infant death syndrome, aseptic meningitis, juvenile diabetes, autism, learning disabilities, hyperactivity, and such other illnesses and conditions as the Commission may choose to review; and

(B) the potential relationship between radiculoneuritis and MMR and other vaccines containing rubella.

(2) The review under paragraph (1) shall include notice and opportunity for a public hearing and consideration of written information submitted by the public.

(3) Not later than 3 years after the date of enactment of this title, the Commission shall make and publish the following specific findings or determinations:

(A) Whether each of the illnesses or conditions listed in subparagraph (A) or (B) of paragraph (1), as the case may be, can reasonably be determined in some circumstances to be caused or significantly contributed to by the vaccines specified in such subparagraph.

(B) For each illness or condition for which a finding of causation or contribution is made under subparagraph (A), the circumstances under which such causation or contribution can reasonably be determined to occur.

(C) For each illness or condition for which a finding of causation or contribution is made under subparagraph (A), the time periods within which the first symptom or manifestation of onset of each such illness or condition can reasonably be determined to occur after pertussis vaccination.

(g) As soon as practicable, but not later than 1 year after the date of enactment of this title, the Commission shall—

(1) conduct and support a broad study of the risks to children associated with each childhood vaccine; and

(2) make recommendations to the Secretary concerning—

(A) the circumstances under which any childhood vaccine should not be administered;

(B) the circumstances under which administration of any childhood vaccine should be delayed beyond its usual time of administration; and

(C) the groups, categories, or characteristics of potential recipients of any childhood vaccine who may be at significantly higher risk of major adverse reaction to such childhood vaccine than the general population of potential recipients.

(h) For the activities of the Commission under this title, there are authorized to be appropriated such sums as may be necessary for each of the fiscal years 1987, 1988, 1989, 1990, and 1991.

RECORDING AND REPORTING OF INFORMATION

SEC. 2102. (a) Each health care provider who administers a childhood vaccine to any individual shall record, or insure that there is recorded, in such individual's permanent medical record (or in a permanent office log or file to which the individual, parent, or legal guardian shall have access upon request) with respect to each such childhood vaccine—

(1) the date of administration of the childhood vaccine;

(2) the manufacturer and lot number of the childhood vaccine;

(3) the name of the health care provider administering the childhood vaccine; and

(4) any other identifying information on the childhood vaccine required pursuant to regulations promulgated by the Secretary.

(b)(1) Any health care provider who, after the date of enactment of this title, administer a childhood vaccine and who is notified or otherwise becomes aware that the recipient of the childhood vaccine has suffered a complication of immunization shall comply with the reporting requirements of paragraph (2).

(2) Any health care provider to whom this subsection applies shall, as expeditiously as practicable, report to the Centers for Disease Control the occurrence of complication of immunization and all other information relevent to such complication, including—

(A) a specification of the type of childhood vaccine administered;

(B) the time period after administration of the childhood vaccine within which such complication occurred;

(C) the manufacturer and lot number of the childhood vaccine; and

(D) the information described in paragraphs (3) and (4) of subsection (a).

(3) If—

(A) the recipient of a childhood vaccine suffers a complication of immunization;

(B) such complication occurs within 20 days after the administration of the childhood vaccine; and

(C) the health care provider receives oral or written notification or otherwise becomes aware of the occurrence of such complication,

the health care provider shall record, or insure the recording of, the symptom or manifestation of the complication and all other relevent information in the childhood vaccine recipient's permanent medical record.

(4) Each health care provider and vaccine manufacturer shall report to the Secretary such information as may be required, by regulation promulgated by the Secretary, to be reported, respecting—

(A) possible occurrences, with respect to any childhood vaccine, of—

(i) illnesses, disabilities, injuries, or conditions relating to the administration of such childhood vaccine; and

(ii) symptoms and manifestations of such illnesses, disabilities, injuries, or conditions; and

(B) the time periods after the inoculation of such childhood vaccines within which such possible occurrences of illnesses, disabilities, injuries, symptoms, and manifestations may occur.

(c)(1) Information which is in the possession of the Federal Government and State and local governments under this section and which may identify an individual shall not be made available under section 552 of title 5, United States Code, or otherwise, to any person except—

(A) the individual who received the childhood vaccine; or

(B) the parent, legal guardian, or authorized legal representative of such individual.

(2) For purposes of this section, the term "information which may identify an individual" shall be limited to the name, street address, telephone number, and actual medical records of the individual who received a childhood vaccine, and of that individual's parent or legal guardian, and shall not include the locality and State of inoculation, the name of the health care provider who administered the childhood vaccine, the date of the vaccination, or information concerning any reported symptom, manifestation, illness, disability, injury, or condition.

(3) Except as provide in paragraph (1), all information reported under this section shall be available to the public.

(d) Compliance by a physician or other health care provider with requirements of this section shall not be construed as an admission of this section shall not be construed as an admission of liability by such physician or other health care provider, and the fact of such compliance shall not be admitted in evidence for the purpose of establishing culpability of any such physician or health care provider in any civil action in tort brought against such physician or other health care provider. The preceding sentence does not preclude the admission into evidence in any civil action in tort of the content of such recorded or reported information if the individual with respect to whom the record or report was made consents to such admission.

RULES WITH RESPECT TO CHILDHOOD VACCINE ADMINISTRATION

SEC. 2103. (a)(1) After receiving and considering the recommendations of the Commission under section 2101(g), the Secretary shall by rule, after notice and opportunity for public hearing and consideration of all relevant medical and scientific information, specify—

(A) the circumstrances under which any childhood vaccine should not be administered;

(B) the circumstances under which administration of any childhood vaccine should be delayed beyond its usual time of administration; and

(C) the groups, categories, or characteristics of potential recipients of any childhood vaccine who may be at significantly higher risk of major adverse reaction to such childhood vaccine than the general population of potential recipients.

(2) The Secretary shall periodically, but at least every 3 years after promulgating the rule required under paragraph (1), review and revise such rule in accordance with the procedures set forth in such paragraph, unless the Secretary finds that on the basis of all relevant information, no revision of such rule is warranted and publishes such finding in the Federal Register.

(b) The Secretary shall widely disseminate the information contained or referenced in the rule required under subsection (a), to—

(1) physicians and other health care providers;

(2) professional health associations;

(3) State and local governments and agencies; and

(4) other relevant entities.

PARENT INFORMATION

SEC. 2104. (a) Not later than 1 year after the date of enactment of this title, the Secretary shall develop parent information materials for distribution by health care providers to the parents or legal guardians of any child receiving a childhood vaccine.

(b) Such materials shall be developed—

(1) after notice to the public and an opportunity for a public hearing; and

(2) in consultation with the Commission, appropriate health care providers and parent organanizations, the Food and Drug Administration, and the Centers for Disease Control.

(c) The information in such materials shall be presented in understandable terms and shall include—

(1) the frequency, severity, and potential long-term effects of the disease to be prevented by the childhood vaccine;

(2) the symptons or reactions to the childhood vaccine which, if they occur, should be brought to the immediate attention of the health care provider;

(3) precautionary measures parents should take to reduce the risk of any major adverse reactions to the childhood vaccine that may occur;

(4) early warning signs or symptoms to which parents should be alert as possible precursors to such major adverse reactions;

(5) a description of the manner in which parents should monitor such major adverse reactions, including a form on which

reactions can be recorded to assist parents in reporting information to appropriate authorities;

(6) a specification of when, how, and to whom parents may report any major adverse reaction;

(7) the contraindications to (and bases for delay of) the administration of the childhood vaccine;

(8) an identification of the groups, categories, or characteristics of potential recipients of the childhood vaccine who may be at significantly higher risk of major adverse reaction to the childhood vaccine than the general population;

(9) a summary of any relevant State and Federal laws concerning the childhood vaccine, including information on the number of vaccinations required for school attendance and the schedule recommended for such vaccinations; and

(10) such other relevant information as may be determined by the Secretary.

MANDATE FOR SAFER CHILDHOOD VACCINES

SEC. 2105. (a) The Secretary shall—

(1) promote the development or refinement of childhood vaccines that result in fewer and less serious adverse reactions; and

(2) make or assure improvements in, and otherwise to use the authorities of the Secretary with respect to, the licensing, manufacturing, processing, testing, labeling, warning, use instructions, distribution, storage administration, field surveillance, adverse reaction reporting, and recall of reactogenic lots or batches, of childhood vaccines, and research on childhood vaccines, in order to reduce the risks of adverse reactions to childhood vaccines.

(b) Within 2 years after the date of enactment of this Act, and every 2 years thereafter, the Secretary shall prepare and transmit to the Committee on Labor and Human Resources of the Senate and the Committee on Energy and Commerce of the House of Representatives a report describing the actions taken pursuant to subsection (a) during the preceding 2-year period.

(c) Not later than 1 year after the date of enactment of this title and after consultation with the Commission and with other appropriate entities, the Secretary shall review the warnings, use instructions, and precautionary information presently issued by manufacturers of diphtheria, pertussis, tetanus, measles, mumps, rubella, and polio vaccines and shall determine whether such warnings, instructions, and information adequately warn health care providers of the nature and extent of dangers posed by such vaccines. If the Secretary determines such warnings, instructions, and information are inadequate for this purpose in any respect, the Secretary shall at the same time require the manufacturers to revise and reissue such warnings, use instructions, and precautions as expeditiously as practical, but not later than 18 months after the date of enactment of this title. In conducting the review required by this subsection, the Secretary shall request comments from the public.

RESEARCH FOR A SAFE PERTUSSIS VACINE

SEC. 2106. (a) The Secretary shall conduct studies to identify and develop new, safe, and effective pertussis vaccines, including—

(1) laboratory studies of the immune response to, and diagnosis of, pertussis;

(2) phase I safety and immunogenicity studies;

(3) field trials of the safety and efficacy of new pertussis vaccines; and

(4) epidemiologic studies of the incidence of serious reactions following immunization with new pertussis vaccines.

(b) To carry out this section, there are authorized to be appropriated $11,000,000 for fiscal year 1987 and $1,000,000 for fiscal year 1988.

REPORTS RELATING TO CHILDHOOD VACCINES

SEC. 2107. (a) The provisions of section 505(k) of the Federal Food, Drug, and Cosmetic Act with respect to records required to be maintained and reports required to be made by applicants, and the requirements imposed by regulations issued under that section, shall apply to persons holding licenses under section 351 of the Public Health Service Act for childhood vaccines.

(b) The Secretary shall take appropriate actions to coordinate the receipt, collection, and evaluation of reports submitted to the Centers for Disease Control under section 2102 and reports submitted to the Food and Drug Administration under this section in order to avoid, insofar as practicable, duplicate reporting of the same events resulting from the administration of vaccines and in order to ensure that all such reports are available for evaluation by the Centers for Disease Control.

DEFINITIONS

SEC. 2108. For purposes of this title:

(1) The term "Commission" means the Advisory Commission on Childhood vaccines established under section 2101.

(2) The term "childhood vaccine" means a vaccine against measles, mumps, rubella, diphtheria, pertussis, tetanus, or polio.

(3) The term "health care provider" means any licensed health care professional, organization, or institution, whether public or private (including Federal, State, and local departments, agencies, and instrumentalities) under whose authority a childhood vaccine is administered.

(4) The term "medical and scientific information" includes epidemiologic, clinical, biostatistical, pathological, toxicologic, and other laboratory data and case study information, observations, studies, and reports in peer-reviewed literature or official government publications, as well as relevant unpublished information, data, studies, and observations.

(5) The term "MMR" means a vaccine containing material intended to prevent or confer immunity against measles, mumps, and rubella.

(6) The term "vaccine manufacturer" means any corporation, organization, or institution, whether public or private (including Federal, State, and local departments, agencies, and instrumentalities), which manufactures, processes, or distributes under its label any childhood vaccine, except that for purposes of section 351, such term shall include the manufacturer's sales or distribution subsidiary or representatives.

SEVERABILITY

SEC. 2109. In the event any portion of this title is declared or held unconstitutional or invalid, all remaining portions of this title shall remain unaffected, and in force and effect.

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